# Lower urinary tract symptoms in men: the TRIUMPH cluster RCT

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Jo Worthingtono,<sup>1†</sup> Jessica Frosto,<sup>1†</sup> Emily Sandersono,<sup>1</sup> Madeleine Cochraneo,<sup>1</sup> Jessica Wheelero,<sup>2</sup> Nikki Cotterillo,<sup>3</sup> Stephanie J MacNeillo,<sup>1</sup> Sian Nobleo,<sup>2</sup> Miriam Averyo,<sup>4</sup> Samantha Clarkeo,<sup>5</sup> Mandy Fadero,<sup>4</sup> Hashim Hashimo,<sup>6</sup> Lucy McGeagho,<sup>7</sup> Margaret Macaulayo,<sup>4</sup> Jonathan Reeso,<sup>8</sup> Luke Robleso,<sup>7</sup> Gordon Tayloro,<sup>9</sup> Jodi Tayloro,<sup>1</sup> Joanne Thompsono,<sup>5</sup> J Athene Laneo,<sup>1</sup> Matthew J Riddo<sup>10</sup> and Marcus J Drakeo<sup>6,11*</sup> on behalf of the TRIUMPH study group
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### **Disclosure of interests**

**Full disclosure of interests:** Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GVBC3182.

<sup>&</sup>lt;sup>1</sup>Bristol Trials Centre, Population Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK

<sup>&</sup>lt;sup>2</sup>Population Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK <sup>3</sup>School of Health and Social Wellbeing, College of Health, Science and Society, University of the West of England, Bristol, UK

<sup>&</sup>lt;sup>4</sup>School of Health Sciences, University of Southampton, Southampton, UK

<sup>&</sup>lt;sup>5</sup>Clinical Research Centre, Southmead Hospital, North Bristol NHS Trust, Bristol, UK

<sup>&</sup>lt;sup>6</sup>Bristol Urological Institute, Southmead Hospital, North Bristol NHS Trust, Bristol, UK

<sup>&</sup>lt;sup>7</sup>National Institute for Health and Care Research Bristol Biomedical Research Centre, University Hospitals Bristol and Weston NHS Foundation Trust, University of Bristol, Bristol, UK

<sup>&</sup>lt;sup>8</sup>Tyntesfield Medical Group, Bristol, UK

<sup>&</sup>lt;sup>9</sup>Patient and public involvement representative, UK

<sup>&</sup>lt;sup>10</sup>Centre of Academic Primary Care, Population Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK

<sup>&</sup>lt;sup>11</sup>Translational Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK

<sup>\*</sup>Corresponding author Marcus.Drake@bristol.ac.uk †Contributed equally

Primary conflicts of interest: Stephanie J MacNeill is an active member of the Health Technology Assessment (HTA) General Committee. Hashim Hashim reports personal fees from Medtronic plc (Dublin, Ireland), Astellas Pharma Inc. (Tokyo, Japan), Allergan plc (Dublin, Ireland) and Boston Scientific (Marlborough, MA, USA), outside the submitted work. Jonathan Rees is chairperson of the Primary Care Urology Society, which has received non-promotional sponsorship for annual meetings from Ferring Pharmaceuticals (Saint Prex, Switzerland), Astellas Pharma, NeoTract Inc. (Pleasanton, CA, USA) and iMEDicare Ltd (London Colney, UK). He has also received speaker fees from Astellas Pharma. J Athene Lane reports receiving funding from the clinical trials unit of which she was co-director, and is currently an active member of the National Institute for Health and Care Research (NIHR) Clinical Trials Unit Standing Advisory Committee. Matthew J Ridd was, during the course of the study, on several NIHR committees, namely the HTA General Committee and the Evidence Synthesis Programme Grants Committee, and is currently on the Evidence Synthesis Programme Advisory Group. Marcus J Drake reports personal fees from Astellas Pharma and Pfizer Inc. (New York, NY, USA), outside the submitted work.

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### Plain language summary

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# **Plain language summary**

rinary problems among men become more common with age. Nearly one-third of all men aged > 65 years experience some urinary symptoms, which can have a substantial effect on their daily lives. Symptoms include needing to pass urine more often, urgently or during the night, and difficulties in passing urine.

Men are usually diagnosed and treated by their general practitioner, and should be offered advice on controlling their symptoms themselves (e.g. lifestyle changes and exercises) before trying tablets or surgery. However, it is not known how helpful such advice is, and how general practices can effectively provide it. Thirty general practices in the West of England and Wessex took part in the study. Practices were split into two groups, with each practice providing either the TReatling Urinary symptoms in Men in Primary Health care using non-pharmacological and non-surgical interventions care package or the practice's usual care to all of its patients in the trial. The TReatling Urinary symptoms in Men in Primary Healthcare using nonpharmacological and non-surgical interventions care package included a booklet of advice to help control urinary symptoms, with a nurse or healthcare assistant directing men to relevant sections according to their symptoms, and providing follow-up contacts. We mainly assessed the benefits of the TReatling Urinary symptoms in Men in Primary Healthcare using nonpharmacological and non-surgical interventions care package, compared with usual care, by using a questionnaire on urinary symptoms completed by participants.

A total of 1077 men with urinary symptoms that bothered them joined the study. The main result was that men reported greater improvement in urinary symptoms with the TRIUMPH care package than with usual care, 12 months after joining the study. We also found that men receiving the TRIUMPH care package had a slight improvement in quality of life and outlook on their urinary symptoms. There was no difference between the two groups in the number of patients referred to hospital for treatment, the type, number and severity of side effects or cost to the NHS. Overall, the TRIUMPH care package was more effective in treating men with urinary symptoms than usual care by their general practice.

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